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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,326	04/01/2004	Jerry Henslee	5972.US.D3	9145

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
01/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/816,326	HENSLEE ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 6-8 are pending.

Claims 6-8 have been amended.

Claims 6-8 are examined on the merits.

Withdrawn Rejection

Claim Rejections - 35 USC § 102

2. Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0082216 (filed January 8, 2001). US patent application publication #2002/0082216 discloses Applicants' mammaglobin (SEQ ID NO: 5), which is the same as the publication's sequence 27, see SCORE results, rapbm database, result 1; Figure 2; page 2, section 0027; and page 26. This molecule is the human mammaglobin amino acid sequence. The publication discloses "...methods for detecting of RNA encoding mammaglobin..." and consequent detection of breast cancer, see abstract.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The rejection of claims 6-8 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0009738 (filed April 2, 2001/ IDS reference A5 submitted May 18, 2005) is maintained.

Applicants set forth the criteria for establishing a rejection for anticipation under section 102 and aver the cited prior art does not meet these criteria, see page 3 of Remarks submitted October 28, 2007, 4th paragraph. "Specifically, the '738 application does not disclose or suggest a method of detecting breast cancer in a patient...detecting the presence of at least two mRNA molecules which produce at least two polypeptides or translation products selected from...mammaglobin (SEQ ID NO: 5), BU101 (SEQ ID NO: 6) and BS106 (SEQ ID NO: 8)", see page 3 of Remarks, last sentence. Hence, Applicants assert the rejection is moot and should be withdrawn. Applicants' points of view and arguments have been carefully considered, but found unpersuasive.

The publication is replete with methodologies disclosing the detection of at least two mRNA molecules, which encode SEQ ID NO: 6 and SEQ ID NO: 8 in order to

detect the presence of breast cancer, see page 8 beginning at section 0130 until section 0147 bridging pages 9 and 10. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082216 (filed January 8, 2001), and further in view of U.S. Patent Application Publication 2002/0009738 (filed April 2, 2001/ IDS reference A5 submitted May 18, 2005). US patent application publication #2002/0082216 teaches Applicants' mammaglobin (SEQ ID NO: 5), which is the same as the publication's sequence 27, see SCORE results, rapbm database, result 1; Figure 2; page 2, section 0027; and page 26. This molecule is the human mammaglobin amino acid sequence. The publication teaches "...methods for detecting of RNA encoding mammaglobin..." and consequent detection of breast cancer, see abstract.

"Polynucleotides may be prepared using any of a variety of techniques...Such polynucleotides may be amplified via polymerase chain reaction (PCR).", see page 4, section 0051. "One preferred assay employs RT-PCR, in which PCR is applied in conjunction with reverse transcription. Typically, RNA is extracted from a sample tissue and is reverse transcribed to produce cDNA molecules. PCR amplification using at least

one specific primer generates a cDNA molecule, which may be separated and visualized using, for example, gel electrophoresis. Amplification may be performed on samples obtained from biological samples taken from a test patient and an individual who is not afflicted with a cancer.", see page 14, section 0144.

Translation products or the proteins encoded by the disclosed nucleic acids can be detected, with a monoclonal antibody or fragment that specifically bind to the breast tumor proteins, see abstract; page 4, section 0049; page 5, section 0071; and page 14, section 0136.

U.S. Patent Application Publication 2002/0009738 does not teach the claimed method wherein the presence of at least two mRNA molecules is detected. However, U.S. Patent Application Publication 2002/0082216 teaches methodologies disclosing the detection of at least two mRNA molecules, which encode SEQ ID NO: 6 and SEQ ID NO: 8 in order to detect the presence of breast cancer, see page 8 beginning at section 0130 until section 0147 bridging pages 9 and 10. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to detect an additional diagnostic marker, which is associated with effective cancer diagnosis. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both references, "to improve sensitivity, multiple breast tumor protein markers may be assayed within a given sample" and it is routine to use combinations in order to determine optimal sensitivity, see publication '216, page 15, section 0147; and publication '738, section 0147 bridging pages 9 and 10.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner normally works a flexible schedule, but can usually be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
27 December 2007